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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/450,511

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KAORU ARAI

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12/06/2001

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EXAMINER

MAYES, MELVIN C

ART UNIT

PAPER NUMBER

1734

DATE MAILED: 12/06/2001

8

Please find below and/or attached an Office communication concerning this application or proceeding.

MF-8

Office Action SummaryApplication No.
09/450,511

Applicant(s)

Arai et al.

Examiner

Curtis Mayes

Art Unit

1734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for ReplyA SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 16, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 and 7 20) ☐ Other:

Art Unit: 1734

DETAILED ACTION

Claim Rejections - 35 USC § 103

(1)

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(2)

Claims 1-8 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. in view of Ogawa et al.

Kim et al. discloses a method of making a ceramic vertebrae prothesis comprising: providing a dried dense material to correspond to the center portion, providing a dried porous material to correspond to the circumferential portion; adhering the dried dense material to the dried porous material by an apatite slurry; and heating the assembly. The ceramic can be calcium phosphate of Ca/P ratio of 1.0 to 2.0 such as hydroxyapatite and the porous portion is made to have a porosity of 20-55%. Kim et al. disclose heating hydroxyapatite at 1000-1200°C to obtain a final product (col. 4, lines 18-38, col. 5, lines 1-6 and 13-26).

Ogawa et al. teach that hydroxyapatite can be synthesized by various known methods including a wet method in which phosphoric acid or a water-soluble phosphate salt is reacted with a water-soluble calcium compound in an aqueous solution and a dry method in which phosphoric acid compound is reacted with a calcium compound under high temperatures. Ogawa et al. teach

Art Unit: 1734

making a hydroxyapatite slurry by dropwise adding a phosphoric acid solution to a calcium hydroxide slurry (col. 3, lines 31-38, col. 6, lines 32-40).

It would have been obvious to one of ordinary skill in the art to have adhered the dried dense and porous material of hydroxyapatite by an apatite slurry by using a slurry prepared by adding a phosphoric acid solution to a calcium hydroxide slurry as taught by Ogawa et al. as one of the known methods of making a hydroxyapatite slurry. By using a hydroxyapatite slurry prepared by adding a phosphoric acid solution to a calcium hydroxide slurry, as taught by Ogawa et al. as a known wet method of making hydroxyapatite, a slurry prepared by merely adding a phosphoric compound to a calcium compound slurry, as claimed in Claim 1, and a slurry of particles dispersed in the absence of organic components, as claimed in Claim 19, is obviously prepared.

In the event any differences can be shown for the product of the product-by-process claims 17 and 18, as opposed to the product taught by the combination of Kim et al. and Ogawa et al. such differences would have been obvious to one of ordinary skill in the art as a routine modification of the product in the absence of a showing of unexpected results; see also *In re Thorpe*, 227 USPQ 964 (CAFC 1985).

When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or 103 of the statute is appropriate. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes

Art Unit: 1734

put before it and then obtain prior art products and make physical comparisons therewith. A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their particular nature than when a product is claimed in the conventional fashion. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972); *In re Fessmann*, 180 USPQ 324 (CCPA 1974).

(3)

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of JP 2-225382.

JP '382 teaches that apatite of average particle size of 0.1 to 15 microns is suitable for applying between apatite products for bonding the products. JP '382 also teaches that the apatite is provided such that it is 5 to 40 wt% of an aqueous solution used for a bonding material (Abstract).

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by providing the amount of apatite in the bonding slurry in an amount in the range of 5 to 40wt%, and thus encompassing the range of 0.1 to 20vol% as claimed in Claim 9, as taught by JP '382 as the amount of apatite in an aqueous solution for a bonding material.

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by adding the providing particles of average grain size in the range of 0.1 to 15 microns in the slurry, and thus 0.05 to 0.5 microns as claimed in Claim 10, as taught

Art Unit: 1734

by JP '382 as the average particle size of apatite suitable for applying between apatite products for bonding the products

Response to Arguments

(4)

Applicant's arguments filed November 16, 2001 have been fully considered but they are not persuasive.

Applicant argues that the references do not disclose the slurry being synthesized by merely adding a phosphoric compound to a calcium compound slurry, as now claimed, argues that Kim is silent as to whether the slurry is a slurry of dispersed primary particles synthesized by merely adding a phosphoric compound to a calcium compound slurry and argues that the prior art of record either discloses the inclusion of organic components or is silent with respect thereto. Applicant argues that the products of Claims 17 and 18 are not taught or suggested in the prior art in view of the differences in the slurry.

(5)

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection, applied because of the amendment to Claim 1. Kim discloses using an apatite (i.e. hydroxyapatite) slurry for bonding hydroxyapatite portions. As taught by Ogawa et al., a hydroxyapatite slurry is made by the known method of dropwise adding a phosphoric acid solution to a calcium hydroxide slurry. Thus providing the apatite slurry in the

Art Unit: 1734

method of Kim by adding a phosphoric acid solution to a calcium hydroxide slurry, and thus in the absence of organic components, would have been obvious to one of ordinary skill in the art.

With respect to the product-by-process claims 17 and 18, the product of the prior art, a ceramic vertebrae prothesis formed of heating two hydroxyapatite portions joined by an apatite slurry reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, which is bone replacement material formed by sintering two ceramic bodies between which a slurry synthesized by merely adding a phosphoric compound to a calcium compound slurry has been interposed.

Conclusion

(6)

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The references disclose that hydroxyapatite slurry is made by reacting phosphoric acid with calcium hydroxide in an aqueous solution.

(7)

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1734

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

(8)

Applicant is encouraged to FAX After Final Amendments (37 CFR 1.116) to expedite delivery to the Examiner. The Tech Center 1700 official facsimile number for After Final faxes is (703) 872-9311. A duplicate mailed copy of the facsimile transmission is not required and will only serve to delay processing of your application. The facsimile number for other official papers is (703) 872-9310, and the fax number for unofficial papers is (703) 305-7115.

When filing a FAX in Tech Center 1700, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communication with PTO that are not for entry into the file of the application. This will expedite processing of your papers. If applicant prefers to mail in After Final correspondence it is highly recommended that such be mailed BOX AF which will also facilitate processing from the mailroom and within Tech Center 1700.

Art Unit: 1734

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Curtis Mayes, whose telephone number is (703) 308-1977. The examiner can be reached between the hours of 7:30 AM and 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino, can be reached on (703) 308-3853. The receptionist number for Tech Center 1700 is (703) 308-0661.


CURTIS MAYES
PRIMARY EXAMINER

Art Unit 1734
December 3, 2001